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AstraZeneca UK Limited, Kudos Pharmaceuticals Limited,
The University of Sheffield, and
MSD International Business GmbH*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA PHARMACEUTICALS
LP, ASTRAZENECA UK LIMITED,
KUDOS PHARMACEUTICALS LIMITED,
THE UNIVERSITY OF SHEFFIELD, and
MSD INTERNATIONAL BUSINESS
GMBH,

Plaintiffs,

v.

NATCO PHARMA LIMITED and NATCO
PHARMA INC.,

Defendants.

C.A. No. 3:23-cv-00796 (RK)(TJB)

**STIPULATION AND ORDER OF
DISMISSAL OF CERTAIN COUNTS**

WHEREAS, Plaintiff AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets; and

WHEREAS, Defendants Natco Pharma Limited and Natco Pharma, Inc. (collectively, “Defendants”) submitted Abbreviated New Drug Application (“ANDA”) No. 218044 (“Natco’s ANDA”) to obtain approval from the United States Food and Drug Administration (“FDA”) to make, use, offer for sale, or sell within the United States, or import into the United States generic versions of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg (hereinafter, “Natco’s ANDA Products”); and

WHEREAS, as relevant to this Stipulation, Natco’s ANDA contained so-called “Paragraph IV Certifications” pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that U.S. Patent Nos. 7,449,464 (“the ’464 patent”), 8,475,842 (“the ’842 patent”) and 8,859,562 (“the ’562 patent”) are invalid or would not be infringed by Natco’s ANDA Products; and

WHEREAS, Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, Kudos Pharmaceuticals Limited, The University of Sheffield and MSD International Business GmbH (collectively, “Plaintiffs”) filed an action against Defendants for infringement of the ’464 patent, the ’842 patent, and the ’562 patent under 35 U.S.C. § 271 (ECF No. 1); and

WHEREAS, after the Complaint was filed in this action, the United States Patent and Trademark Office issued U.S. Patent No. 11,633,396 (“the ’396 patent”); and

WHEREAS, on May 19, 2023, the ’396 patent was listed in the *Approved Drug Products with Therapeutic Equivalent Evaluations* (“Orange Book”) in connection with NDA No. 208558; and

WHEREAS, Defendants have filed counterclaims against Plaintiffs for the ’464 patent, the ’842 patent, the ’562 patent and the ’396 patent (ECF No. 36); and

WHEREAS, on October 17, 2023, Kudos Pharmaceuticals Limited, AstraZeneca UK Ltd., AstraZeneca Pharmaceuticals LP, and MSD International Business GmbH executed a Covenant Not to Sue with respect to the '842 patent and the '396 patent.

IT IS HEREBY STIPULATED AND AGREED BY AND BETWEEN THE RESPECTIVE PARTIES THAT:

1. The parties agree that, as a result of the foregoing, all claims, counterclaims, and affirmative defenses between Plaintiffs and Defendants with respect to the '842 patent and the '396 are hereby **DISMISSED WITHOUT PREJUDICE** pursuant to Federal Rule of Civil Procedure 41(a)(1), including
 - a. Counts III and IV of Plaintiffs' Complaint, ECF No. 1;
 - b. Defendants' counterclaim Counts III, IV, VII and VIII of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement, ECF No. 36;
 - c. Defendants' affirmative defenses of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement, ECF No. 36, with respect to the '842 patent and the '396 patent; and
 - d. Defendants' Prayer for Relief of Defendants' First Amended Answer, Affirmative Defenses and Counterclaims to Complaint for Patent Infringement (a), (b), ECF No. 36, with respect to the '842 patent and the '396 patent;
2. For clarity and the avoidance of doubt, this Stipulation and Order does not relate to, dismiss, or in any way affect any claims, counterclaims, or affirmative defenses pending between Plaintiffs and Defendants relating to the '464 patent or the '562 patent.
3. Each party shall bear its own costs, disbursements, and attorney fees.

Dated: November 8, 2023

s/Charles H. Chevalier

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SO ORDERED THIS 13th day of November 2023.



The Honorable Robert Kirsch, U.S.D.J.